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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/919,360 | 07/30/2001 | Leroy E. Hood | P-IS 4627 | 2535 |
| 23601 | 7590 | 11/17/2004 | EXAMINER | |
| CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122 | | | MARSCHEL, ARDIN H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,360

Applicant(s)

HOOD ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8-32, 34 and 36-55 is/are pending in the application.
- 4a) Of the above claim(s) 3, 17-29 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 8-16, 30-32, 34, 36-44 and 46-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6, 8-32, 34, & 36-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date (1 sheet).
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 8/24/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

ELECTION BY ORIGINAL PRESENTATION

Newly submitted claim 45 is directed to an invention that is independent or distinct from the invention originally elected and claimed invention as being directed to a non-elected species as set forth in the previous office action, mailed 9/22/03, and non-elected in applicants' response, filed 11/24/03.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 45 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6, 8-16, 30-32, 34, 36-44, and 46-55 are rejected under 35

U.S.C. 102(a) and (e)(2) as being clearly anticipated by Friend et al. (P/N 6,218,122).

This rejection is reiterated and maintained from the previous office action, mailed 2/24/04, and as necessitated by amendment regarding newly added claims which cite limitations from within claims previously pending. Applicants argue that the Declaration, filed 8/24/04, of applicants describe distinguishing limitations in the instant claims compared to Friend et al.

Item # 3) of said Declaration firstly argues that interpolation of unidimensional analysis is only described in Friend et al. In response, firstly the instant claims are not limited to exclude interpolation. Secondly, various analyses within Friend et al. were previously pointed to as illustrated by graphs therein which are 2-dimensional graphs. Such analyses are thus multidimensional as instantly claimed thus making this argument non-persuasive.

Item # 4) of said Declaration argues that the interpolated response curves are unidimensional functions for a single cellular constituent. In response Figures 1-3 were exemplified in the previous office action, mailed 2/24/04 as multidimensional. Considering Figure 1, for example, reveals that each data point therein corresponds to two parameter values, one being expression ratio and the other being intensity. Even the expression ratio is itself a ratio of two numbers and is multidimensional parameter.

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Thus, applicants' characterization of these values and analyses in Friend et al. as being unidimensional fails to correspond to the actual basis descriptions in Friend et al.

Item # 5) of said Declaration argues further that the claimed methods are fully multidimensional. This is acknowledged but as noted regarding Item # 4) of said Declaration discussed above is not distinguished from the reference. In Item # 5) of said Declaration the phrase "reference expression region" is defined as a region of multidimensional space classified using one or more statistical methods. In response the expression profiles of Friend et al. are regions of expression data wherein the data is defined by statistical methods including correlation between expression and disease state(s) as previously pointed to in column 6, line 48, through column 8, line 62, wherein specifically such correlation is cited in column 8, lines 48-51. Thus, reference expression region practice is also reasonably set forth in Friend et al. corresponding to this specific limitation in the instant claims. It is noted that nothing in applicants' arguments point to a definition of "reference expression region" which excludes the Friend et al. correlation as noted above.

Item # 6) of said Declaration argues also that a multidimensional method as shown in Example I (pages 136-137) also illustrated in Exhibit A distinguishes the instant invention over Friend et al. In response, Exhibit A depicts a particular type of graphical representation wherein two molecules are evaluated with each molecular value being plotted on separate axes of the Exhibit A graph. This is also shown in said Example I via Figure 3 of the instant specification. These are examples of types of multidimensional analysis with graphing but do not negate or exclude the Friend et al.

analyses and graphical representation since terms in the claims are reasonably interpreted via their broadest reasonable interpretation which includes embodiments both of the Friend et al. type as noted above as being multidimensional as well as embodiments of said Example I and Exhibit A. Since these interpretations are both within a reasonable interpretation of the instant claim wording and no definition or claim limitation limits the claims to exclude the Friend et al. type of multidimensional analysis, this argument is non-persuasive.

Item # 7) of said Declaration then discusses Exhibit A as showing perturbation levels for molecules 1 and 2 but does not present any further argument.

Item # 8) of said Declaration argues additionally that the Friend et al. interpolation methods cannot distinguish certain perturbation levels. In response, since applicants' claim wording does not exclude the Friend et al. methods, but rather includes them as discussed above, the argument that particular types of analyses within the instant claims are different from the Friend et al. methods is non-persuasive regarding whether Friend et al. discloses an invention which anticipates the instant claims. Applicants are reminded that a reference which discloses embodiment species of claims under examination anticipates such claims even though the claims may also include other embodiment species which are not disclosed in a reference. This is the case here which still supports the rejection of the broadly worded instant claims based on Friend et al.

Item # 9) of said Declaration restates the above argument regarding a specific type of multidimensional analysis as instantly exemplified but not exclusively claimed.

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The non-exclusiveness of the instant claims still supports this rejection. Applicants are also reminded that broadly worded claims as instantly set forth do not support reading into them exemplified limitations from the specification. Rather broadly worded claims are to be interpreted as reasonably broad as they are worded thus supporting this rejection.

Lastly, applicants argue that white blood cell disclosure in the reference does not support rejection of leukocyte limitations in the instant claims. In response, leukocytes are generally well known to be the alternative name given to white blood cells and thus this argument is non-persuasive. Also, applicants have not set forth any argument as to what distinguishes leukocytes over the well known terminology of these being called white blood cells.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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COMPLETENESS OF RESPONSE

This application contains claims 3, 17-29, and 45 (presently claim 45 has been indicated above as also non-elected) drawn to an invention nonelected with traverse in the Paper filed 11/24/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 11/12/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER

November 12, 2004